K013152

SIGN
Surgical Implant Generation Network

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DEC 2 0 2001

Summary of Safety and Effectiveness
SIGN IM Nail

Substantial Equivalence Information

The SIGN IM Nail if similar to the following Devices:

1. Smith & Nephew "TriGen®" Knee Nail
2. ACE Medical "AIM" Titanium Tibial Nail
3. Synthes "Universal Nail"

All of the devices listed above are similar in design to the SIGN IM Nail system. The safety and effectiveness of the SIGN IM Nail is also based on a long history of use of this type of device in the market place.

Device Description

The SIGN IM Nail system includes Intramedullary nails, Interlocking Screws and Instruments. All components are manufactured from stainless steel. The SIGN IM Nail is available with diameters of 8mm, 9mm, 10mm, 11mm, and 12mm in the following lengths: 150mm, 190mm, 230mm, 270mm, 280mm, 300mm, 320mm, 340mm, 360mm, 380mm, 400. Each nail is made from a solid type 316, ASTM F138, stainless steel bar with distal and proximal bends. Each nail has holes and/or slots at both the distal and proximal ends to accept solid 4.5mm diameter cortical bone screws.

Indications for use

The SIGN IM Nail is indicated for internal fixation of diaphyseal tibial fractures and distal femur fractures including Transverse fractures, oblique and spiral fractures, comminuted fractures, fractures with bone loss, open fractures, corrective osteotomies, pathologic fractures, pseudoarthrosis of the tibial shaft, nonunions, malunions.

The SIGN IM Nail may be removed upon fracture healing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2001

Mr. Doug Donnelly
Regulatory Affairs
Surgical Implant Generation Network
2950 George Washington Way
Richland, Washington 99352

Re: K013132
Trade/Device Name: SIGN IM Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: December 5, 2001
Received: December 7, 2001

Dear Mr. Donnelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Divison of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section VI, Indications For Use

510(k) Number (if known): K013132

Device Name: SIGN IM Nail

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013132

(Optional Format 3-10-98)